REMARKS

Claims 1-23 and 40-55 are currently pending in the application. Claim 1 has been amended. Support for this amendment is found throughout the specification, for example, on page 3, lines 25-26 and page 5, lines 17-19. No new matter has been added.

Applicants thank the Examiner for favorable consideration and allowability of claims 3, 22, 46, 47 and 55. Claim 22 has been rewritten in independent form, as directed by the Examiner. Since the original claim 22 is allowable over prior art and the rewriting only changes the form of the claim, no changes have been made to the scope of the original claim 22. As for the objection to claims 3, 46, 47 and 55, Applicants respectfully request reconsideration in view of the discussion below.

Reconsideration of all claims now pending in the application is respectfully requested.

Status of Examiner's Consideration of Applicants' Supplemental Information Disclosure Statement

Applicants request the Examiner's acknowledgement of the Supplemental Information Disclosure Statement filed on February 12, 2004 with the next Office communication.

I. Rejection under 35 U.S.C. §102 (a)

A. On page 2 of the Office Action, claims 1-2 and 4-21 are rejected under 35 U.S.C. §102 (a) as being anticipated by Li, et al. (U.S. Patent No. 6,231,879). The Examiner again states that Li, et al. disclose an implantable prosthesis (title) comprising

a rigid material (col. 8, lines 16-17) with pores filled with hydrogel (col. 8, lines 5-15) and a structural protein (collagen, col. 6, lines 43-57).

With regard to claim 4, the Examiner notes that collagen is only coated in the pores.

With regard to claims 9-11 and 13, the Examiner cites column 1, lines 14-20 and column 10, lines 39-65.

With regard to claim 14, the Examiner cites column 7, lines 1-4.

With regard to claims 16 and 17, the Examiner notes that the material is an open celled foam having a network of pores (col. 5, lines 46-54).

With regard to claim 18, the Examiner notes that collagen is a nutrient.

With regard to claim 19, the Examiner contends that the reference teaches a device seeded with cells (col. 14, lines 1-2).

Finally, with regard to claims 20 and 21, the Examiner cites column 3-4, lines 64-5.

Applicants respectfully traverse the rejections.

As noted before in the previous response, Li, et al. teach methods of manufacturing implantable biocompatible cell encapsulation devices having a jacket made of a permeable biocompatible material and a foam core with cells dispersed in the foam pores. See abstract. The jacket allows passage of substances up to a predetermined size, but prevents the passage of larger substances, such as mammalian cells. See col. 4, lines 35-36 and claim 1. Preferably, the devices of the invention are immunoisolatory, so that the devices can function for extended periods of time in vivo. Col. 5, lines 4-9. To be immunoisolatory, the surrounding or peripheral region of the

device is constructed to protect the cells with a physical barrier sufficient to prevent detrimental immunological contact between the encapsulated (isolated) cells and the host's immune system, and to prevent harmful substances of the host's body from entering the core of the device. Col. 5, lines 9-16. Any suitable thermoplastic or thermoplastic elastomeric foam scaffold material, preferably polyvinyl alcohol (PVA) sponges, may be preformed for insertion into a pre-fabricated jacket. Col. 8, lines 3-6. PVA sponges are water-insoluble foams formed by the reaction of aerated Poly(vinyl alcohol) solution with formaldehyde vapor as the crosslinker, and the hydroxyl groups on the PVA covalently crosslink with the aldehyde groups to form the polymer network, which are flexible and elastic when wetted and semi-rigid when dried. Col. 8, lines 12-17. The foam scaffold may also be pre-formed and then coated with a cell impermeable jacket. See col. 8, lines 47-48. Any suitable method of sealing the devices may be used, including the employment of polymer adhesives and/or well-known techniques such as crimping, knotting and heat sealing. Col. 9, lines 17-20. If dry sealing is done, a substantially non-porous fitting member is provided which is attached to the membrane encapsulation device with a secure dry seal and the cell-containing solution can be introduced through such fitting member. Col. 9, lines 20-25. Subsequent to filling, the device is sealed by closing the opening in the non-porous fitting. See col. 9, lines 25-27.

The cell encapsulating device of Li, et al. is a device for holding cells. As noted by the above-cited passages, the device is sealed with the cells inside, and the jacket of the sealed device allows or prevents the passage of cells and other materials in or out. See col. 4, lines 35-36. In addition to the foams being flexible and elastic when wet, Li, et al. specifically distinguish itself from prior art uses of hydrogels. See col. 2, lines 59-60.

Thus, contrary to the Examiner's assertions regarding the recited passages of Li, et al. (title, col. 6, lines 43-57, col. 7, lines 5-15, and col. 8, lines 16-17), Li, et al. do not teach an implantable prosthesis comprising a rigid material with pores, with a filler comprising a hydrogel, a structural protein, a bioactive agent, or mixtures thereof, located within the pores, and having a smoother surface for fluid flow, the subject matter of claim 1.

To anticipate a claim, the reference must teach every element of the claim. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Therefore, all claim elements and their limitations must be found in the prior art reference to maintain a rejection based on 35 U.S.C. §102. Applicants respectfully submit that Li, et al. do not teach every element of claim 1, as noted above, and therefore fails to anticipate claim 1.

Dependent claims 2, and 4-21, which are dependent from independent claim 1, were also rejected under 35 U.S.C. §102(a) as being anticipated by Li, et al. While Applicants do not acquiesce with the particular rejections to these dependent claims, it is believed that these rejections are moot in view of the remarks made in connection with independent claim 1. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited references. Therefore, dependent claims 2, and 4-21 are also in condition for allowance.

Applicants respectfully request withdrawal of the rejection of claims 1-2, and 4-21 under 35 U.S.C. §102 (a) as being anticipated by Li, et al.

B. On page 3 of the Office Action, claims 40-45 and 48-54 are rejected under 35 U.S.C. §102 (b) as being anticipated by Solovay (U.S. Patent No. 6,321,879). The Examiner asserts that Solovay discloses an implantable medical device comprising a rigid material (30) having pores (abstract) and a filler (col. 6) comprising hydrogel, a structural protein, a bioactive agent, or mixtures thereof (lines 47-55) to promote cellular attachment and proliferation. With regard to claims 43 and 52, the Examiner asserts that the filled pores inherently present a smooth surface to flow.

Applicants respectfully traverse the rejections.

Solovay discloses an endoprosthesis implant including a stent 20 with an expandable frame 22 and a stent covering 30 having varying porosity in different regions. See abstract. The covering 30 is made of a plurality of woven, braided or knitted fibers. Col. 2, lines 41-42. There is no mention of the covering 30 being made of a rigid material. In fact, since the covering 30 is made of a plurality of woven, braided or knitted fibers, a non- rigid material is implied. Also, since the pores are formed by the plurality of woven, braided, or knitted fibers, the pores extend through the thickness of the covering 30, from the outer surface to the inner surface of covering 30, in either a direct path or through a plurality of interconnected passages through the volume of the covering. Col. 4, lines 11-18. In some cases, the pores may not pass all the way through the covering. Col. 4, lines 18-19. Nevertheless, when there are pores present, Solovay does not disclose or teach that the pores are present only substantially near the surface

of the covering, nor a porous network, with pores extending substantially through a rigid material. Solovay's stent covering 30 has pores that are designed to provide "a lattice for tissue ingrowth allowing cells and blood vessels to travel and grow into and/or through the stent covering 30." (Col. 4, lines 23-25.) "[T]he most important pore parameters [in Solovay] are pore diameters . .pore spacing .. .[t]he corollary to this is pore density." (Col. 4, lines 29-50.) Thus, relative width and density, not depth, are the important pore parameters in Solovay.

Claim 40 provides an implantable medical device comprising a rigid material with pores present substantially close to the surface of the rigid material and a filler comprised of a hydrogel, a structural protein, a bioactive agent, or mixtures thereof, located within the pores to promote cellular attachment and proliferation. Claim 49 provides an implantable medical device comprising a rigid material with pores present substantially extending through the rigid material to form a porous network, and a filler, wherein said filler comprising a hydrogel, a structural protein, a bioactive agent, or mixtures thereof, located within the pores, and said porous network does not provide significant blood flow through the porous material. Solovay does not disclose the subject matter of either claim.

To anticipate a claim, the reference must teach every element of the claim. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Therefore, all

claim elements, and their limitations, must be found in the prior art reference to maintain a rejection based on 35 U.S.C. §102. Applicants submit that since Solovay does not disclose all the claim elements and their limitations of claims 40 and 49, as discussed above, Solovay does not anticipate claims 40 and 49.

Dependent claims 41-45, 48 and 50-54, which are dependent from independent claims 40 and 49, respectively, were also rejected under 35 U.S.C. §102 (a) as being unpatentable over Solovay. While Applicants do not acquiesce with the particular rejections to these dependent claims, it is believed that these rejections are moot in view of the remarks made in connection with independent claims 40 and 49. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features that further distinguish these claims from the cited references. Therefore, dependent claims 41-45, 48 and 50-54 are also in condition for allowance.

Applicants respectfully request withdrawal of the rejection of claims 40-45 and 48-54 under 35 U.S.C. §102 (b) as being anticipated by Solovay.

II. Conclusion

In view of the amendments and reasons provided above, it is believed that all pending claims are in condition for allowance. Applicants respectfully request favorable

reconsideration and early allowance of all pending claims.

If a telephone conference would be helpful in resolving any issues concerning this communication, please contact Applicants' attorney of record, Hallie A. Finucane at (952) 253-4134.

Respectfully submitted,

Altera Law Group, LLC
Customer No. 22865

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By: Hallie A. Finucane
Hallie A. Finucane
Reg. No. 33,172
HAF/JRS/NNQ/mar